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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/349,489	12/02/94	RING	D 0999.001

HM12/0922

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EXAMINER	
EYLER, Y	

ART UNIT	PAPER NUMBER
1642	18

DATE MAILED: 09/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1-File Copy

PTO-90C (REV. 2/95)

☆U.S GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 08/349,489	Applicant(s) Ring
	Examiner Yvonne Eyler	Group Art Unit 1642

☒ Responsive to communication(s) filed on *5/11/99 and 6/21/99*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) *4 and 9-14* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3, 5-8, and 15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request filed on 5/11/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/349489 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 1-15 are pending in the application. Claims 4 and 9-14 have been withdrawn from consideration. Claims 1-3, 5-8 and 15 are under consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

4. The use of the trademarks Quadromas^{R} at page 16 and Immulon^{R} at page 25 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections Withdrawn:

Claim Rejections Maintained and New Grounds of Rejection:

5. The rejection of Claim 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 was rejected for the recitation of cancer antigens 145kD, 40kD, 60kD, 100kD, 42kD, 55kD, 66kD, 75kD, 80kD, and **glycolipid**. The cancer antigens defined only by molecular weight have been removed and therefore, this basis of the rejection is withdrawn. However, the cancner antigen "glycolipid" remains. Without further characterization, it is unclear to what glycolipid the claim refers and encompasses and to what glycolipids it does not.

Claim Rejections - 35 USC § 102

6. The rejection of Claims 1-3, 5-8 and 15 under 35 U.S.C. 102(a) as being anticipated by Weiner et al. (Proc. Am. Soc. Clin. Oncol. 13, March, 1994) is maintained.

7. The rejection of Claims 1-3, 5-8 and 15 under 35 U.S.C. 102(a) as being anticipated by Weiner et al. (Proc. Am. Soc. for Cancer Res. 35:219, March, 1994) is maintained.

Applicant argues that both Weiner et al. abstracts are silent with regard to antibody production to the second antigen and thus do not disclose each and every claimed element. This is not found to be persuasive. The claims are drawn to the adiministration of an amount of bispecific antibody sufficient to induce antibodies to the second antigen. The amounts cited by both Weiner et al. abstracts are the same amounts which are sufficient to induce production of antibodies to the second antigen. Thus, while neither reference measures the antibody production, the amount

bispecific administered meets the limitations and the production of antibodies to the second antigen is an inherent property of administration of that amount.

8. The rejection of Claims 1-3, 5-8, and 15 under 35 U.S.C. 103(a) as being unpatentable over Hsieh-Ma et al. (Cancer Research, 1992) or Weiner et al. (Cancer Research, 1993) or Ring et al. (Breast Epithelial Antigens, 1991) in view of Fanger et al. (Critical Reviews in Immunology, 1992) or Snider et al. (J. Exp. Med. 171:1957-1963, 1990) is maintained.

Hsieh-Ma et al., Weiner et al. and Ring et al. each teach the induction of an immune response, targeted cytolysis, by administration of 2B1 as set forth in the Office Actions of 8/5/97. and 10/18/96 Weiner et al. further teach the induction of an immune response in a patient, a xenograft mouse which meets the definition of patient as specified at page 8 of the instant disclosure.

Hsieh-Ma et al., Weiner et al., and Ring et al. do not specifically teach the induction of antibody production to the second, c-erbB-2, antigen.

Fanger et al, however, teach the known method comprising administration of bispecific antibodies (and optionally antigen) to induce or enhance the production of antibodies to the second antigen. Specifically, Fanger et al. teach that bispecific antibodies targeted to APC cell antigens such as FcgRIII induce production of antibodies to the second antigen.

Similarly, Snider et al. teach a method comprising administration of bispecific antibodies (and optionally antigen) to induce or enhance the production of antibodies to the second antigen.

Specifically, Snider et al. teach that bispecific antibodies targeted to APC cell antigens induce production of antibodies to the second antigen.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to induce an immune response by administering antibodies to FcgRIII and a second antigen (namely 2B1) as taught by Hsieh-Ma et al, Weiner et al. and Ring et al. It would have been further obvious to one of ordinary skill in the art to administer the bispecific antibodies in an amount sufficient to also induce the production of antibodies to the second antigen with a reasonable expectation of success given the teachings of Fanger et al. or Snider et al. and one would have been motivated to do so to optimize the antitumor effect of the treatment.

9. Claim 6 is newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 now recites limitations which were not clearly disclosed in the specification, as filed, and now change the scope of the disclosure. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

The specification, as filed, does not provide support for bispecific antibodies wherein the second antigen binding portion recognizes antigens which bind to antibody 35E2, HB 10789, or HB 10793.

10. Claim 6 is newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 6 now requires use of 3 antibodies, produced by three hybridomas, for which public availability is not ensured. The antibodies/hybridomas are 35E2, HB 10789, and HB 10793. As a required element, the antibodies must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

NO CLAIM IS ALLOWED

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 600pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Yvonne Eyler

Yvonne Eyler, Ph.D.
Primary Examiner
September 20, 1999